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10/532,885	03/03/2006	Gregory Sorensen	125141.00093.MGH2143	2282

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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
09/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	10/532,885	SORENSEN ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8,10,11,13-19 and 29* is/are pending in the application.

4a) Of the above claim(s) *6 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7, 11, 13-19, and 29* is/are rejected.

7)☒ Claim(s) *2-5, 7, 10, and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 6/16/2010, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 6/16/2010, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 6 and 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/4/2009.

Applicant's newly added claim 29 in the response filed 6/16/2010 is acknowledged and entered.

Claims 2-5, 7, 10-11, 13-19, and 29 are the current claims hereby under examination.

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. It is noted that priority to 60/421,736 is claimed in the

declaration filed 2/28/06, but no reference to the provisional application is made in the instant specification.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional

information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Specification

Response to Arguments

Applicant's arguments, filed 6/16/2010, with respect to the objection to the disclosure, have been fully considered and are persuasive because of applicant's arguments and amendments. Therefore the objection has been withdrawn.

Claim Objections

Claims 2-5, 7, 10, and 11 are objected to as they recite "The hazard atlas of claim …" (claim 13 or 5), but parent claim 13 is not directed to a hazard atlas. It is directed to a system comprising a hazard atlas, so it is unclear whether these claims do, in fact, further limit parent claim 13.

Claim Rejections - 35 USC § 112

Response to Arguments

Applicant's arguments, filed 6/16/2010, with respect to the rejection of claims under 35 USC 112 second have been fully considered and are persuasive because of applicant's arguments. Therefore the rejection has been withdrawn.

The following rejection has been modified which has been necessitated by amendment:

Claim Rejections - 35 USC § 103-Modified/Maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-5, 10-11, 13-19, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorensen et al. (US P/N 7,020,578).

The claims are directed to a system for determining a hazard score for a patient having a disorder in a tissue, comprising:

A) a device arranged to obtain or store an image of the patient's tissue, wherein the image comprises a plurality of patient image voxels;

B) a memory or computer-readable medium storing a hazard atlas of a disorder in the tissue, wherein the hazard atlas comprises a plurality of voxels, each voxel representing a hazard value of an extent of deficit caused by damage from the disorder to that voxel of tissue at that location;

C) an output device; and

D) a processor linked to the imaging device, memory, and output device, wherein the processor is programmed to:

(i) obtain the image of a tissue of the patient;

(ii) identify voxels of the patient image that are damaged by the disorder as damaged patient image voxels;

(iii) obtain from the memory or computer-readable medium the hazard atlas of the disorder in the tissue;

(iv) compute a hazard score for the patient, wherein the score is the integration of all damaged patient image voxels weighted by a hazard value corresponding to that voxel location; and

(v) transmit the hazard score to the output device.

With regards to limitations of claims 13 and 29: Sorensen et al. at the abstract and at col. 4, lines 8-10 and lines 64-67 describe obtaining MR image data from acute stroke patients wherein the images comprised patient image voxels, which reads on limitations of part A). Sorensen et al. at col. 5, lines 5-22 describe creating tissue signature maps from the obtained images, which are maps that correlate damaged voxel images with scores and values for "normal" voxel images in order to classify a patient later. Sorensen et al. further describes this process at col. 5, lines 44-67 wherein image processing software was used for processing training data, i.e. brain tissue volumes (voxels) that were clearly infarcted or non-infarcted to develop a tissue signature map, which reads on limitations of part B). Sorensen et al. at col. 6, lines 28-58 further describe wherein patient voxel image data was obtained, used for training for

generating the tissue signature map, i.e. a hazard atlas in the tissue, and a patient was tested for a predicted classification. Sorensen et al. at col. 7, lines 9-10 teach wherein patients were ranked or classified using a numerical integration of using all the voxel data, which reads on limitations of part D) i) - D) - v).

Sorensen et al. suggests, but do not explicitly teach a system for determining a hazard score for a patient, comprising each of the explicit system parts in A)-D) nor outputting the resulting data.

Sorensen et al. suggests this because Sorensen et al. at col. 5, lines 44-67 describes using image processing software for processing the data, which implies the use of a system for performing said method. Sorensen et al. further suggests outputting the data because it is a goal of the invention to have a calculated hazard score which will be used for deciding a treatment.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used a system for performing the method as described above and taught by Sorensen et al. This is because Sorensen et al. do teach using image software analysis for processing data. One of ordinary skill in the art would have immediately recognized that an image software analysis tool would be implemented during its use on a system comprising the claimed system parts. Therefore, one of ordinary skill in the art would have immediately recognized that applying the known technique of using a system for performing the taught method would have yielded predictable results and resulted in an improved method.

It would have further been obvious to one of ordinary skill in the art at the time of the instant invention to have output the calculated patient score, i.e. hazard score of the method taught by Sorensen et al. This is because it is a goal of the taught invention to use the classification data, i.e. score, in order to aid in choosing a therapy for the patient. Thus outputting the resulting data would have been part of the routine procedure of one of ordinary skill in the result. Thus the differences between the prior art and claimed method with respect to outputting was the product not of innovation, but of ordinary skill and common sense.

Sorensen et al. at col. 1, lines 25-26 and col. 4, lines 16-25 teach using MR imaging to obtain images, which reads on claim 14.

Sorensen et al. at col. 2, lines 24-25teach applying the method to patients affected by stroke in the brain, which reads on claims 11 and 15.

Sorensen et al. teach at col. 2, lines 23-25 teach using perfusion image data when determining voxel values, etc. in the taught method, which reads on basing the voxel values on vascular regions as in claim 2.

Sorensen et al. teach at col. 3, lines 25-29 teach determining a risk map, i.e. hazard value, based on patient images and patient response to treatment, i.e. patient behavior, which reads on claim 3.

Sorensen et al. teach at col. 3, 35-45 describe the image data obtained for use in generating the risk maps, which comprises blood volumes determined from MR imaging data, which reads on image data being three-dimensional as in claims 10 and 19.

Sorensen et al. teach at col. 3, lines 45-60 that tissue classification, i.e. probability of infarction, can be determined based on the calculation of an equation, wherein the calculation and result are based on a series of numbers, which reads on the broad and reasonable interpretation of a code, which is a series of numbers as in claims 5, 7, and 16.

Sorensen et al. teach at col. 3, lines 30-32 and col. 4, lines 25-35 combining MRI image data to evaluate infarction risk for each voxel, wherein the combination of image data reads on using an image segmentation method as in claim 18.

Sorensen et al. at col. 4, lines 8-15 and 52-67 and col. 5, lines 1-22 teach using a set of image data from patients that correlates damage and behavior, i.e. response to treatment wherein values were commensurate in scope with damage or infarction as required by claim 4.

Response to Arguments

Applicant's arguments filed 6/16/2010 have been fully considered but they are not persuasive.

Applicant alleges that the “signature maps” or “risk maps” taught by Sorensen are not the same as or an obvious variation of a “hazard atlas” as taught in the instant specification. In particular, applicant alleges that the signature maps or risk maps describe a method of assigning a voxel-by-voxel risk of tissue death in the future whereas the hazard atlas improves upon risk map information mathematically with

location specific information about the impact that a given voxel's death would have on behavior.

Applicant's arguments are not found persuasive because Sorenson at col. 4 lines 53-67 and col. 5, lines 1-5 describe where voxels from the image data were each evaluated with regards to a "normal" appearance and given relative values, whereas the voxels in each image are at specific locations and thus give location specific information. Therefore, the signature maps have been interpreted as reading on a "hazard atlas." With regards to applicant's argument that the hazard atlas evaluates the impact that a given voxel's death would have on behavior is not found persuasive because it is not commensurate in scope with the claimed invention. The claims do not recite a limitation describing the impact on behavior a given voxel's death would have.

Applicant further alleges that nowhere in Sorensen does it describe a compilation of location specific voxel information representing a value of an extent of deficit caused by damage from a disorder to that voxel.

Applicant's argument is not found persuasive because a value may be reasonably and broadly interpreted as one which simply indicates normal and abnormal "states". Sorenson at col. 4, lines 60-64 describe evaluating voxels and identifying those that are "normal." Furthermore, although Sorensen et al. teach generating "risk maps," the generation requires a voxel-by-voxel evaluation on the training data, whereas each voxel gives location specific information. For instance, the method, as described in Fig. 6, and sep 1020, determines the tissue's true outcome, i.e. infarcted or not-infarcted, for each individual voxel and then creates a "risk map" as in step 1030.

Applicant further argues that Sorensen fails to describe anything to do with the integration of damaged patient image voxels weight by a hazard value corresponding to a specific voxel.

Applicant's arguments are not found persuasive because the term weighted has been interpreted as "taking into consideration." The method taught by Sorensen as described throughout and at col. 4-col. 5 evaluates a tissue on a voxel-by-voxel basis. Sorensen et al. describe evaluating the voxels with reference to "normal" or "non-infarcted" and "infarcted." Sorensen further describes evaluating, i.e. integrating, each of the voxels to give an overall tissue evaluation which can be done on a region, hemisphere or the overall tissue, i.e. brain (see col. 13, lines 64-67 through col. 14, lines 1-56). Thus the evaluation of each voxel, which has been evaluated based on damage, reads on the step of integration of all damaged patient image voxels weighted by the hazard value corresponding to that voxel location.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Jason Sims /

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631